K003463

APR 1 1 2001

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	AESCULAP® INC. NOVEMBER 1, 2000

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Trade Name: SOCON® Spinal System

Common Name(s): Pedicle Screw Spine System

Classification Name(s): Pedicle Screw Spinal System

Establishment Name & Registration Number:

Name: Aesculap® Inc.
Number: 2916714

Classification(s): § 888.3070 – Pedicle Screw Spinal System

(a) Identification. Pedicle screw spinal systems are multiple component devices, made of a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allows the surgeon to build an implant system to fit the patients anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors. The devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). (2) Classification. Class II (special controls).

Device Class: Class II for all requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MNH and MNI

Applicant Name & Address:

AESCULAP® Inc.
944 Marcon Blvd.
Allentown, PA 18109
650.876.7000

Company Contact:
Ms. Joyce Thomas
Aesculap® Inc.
944 Marcon Blvd.
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650.876.7000

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Performance Standards (Section 514 compliance):
Food and Drug Administration mandated Performance standards for anterior spine plates are not in effect. AESCULAP® INC. intends to comply with all voluntary Performance Standards applicable to the SOCON® Spinal System. At the present time, various performance standards such as ASTM, ISO, QSR/CGMP and in-house SOP standards are used. In addition, AESCULAP® INC. complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

Special Controls:
Pedicle screw spinal systems must comply with the following special controls

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatibility standard, and
(iv) Labeling which contains the following statements in addition to other appropriate labeling information.

Labeling:
The SOCON® Spinal System discussed is premarket notification will be manufactured by AESCULAP® INC. and labeled as such. The system will be marketed exclusively to healthcare facilities and physicians. In addition, FDA requirements stipulate that the following additional labeling warnings be provided:

"Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

Surgical Technique. The surgical approach of the modified SOCON® Spinal System is identical to the technique used for the original SOCON® Spinal System.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician only.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material in building a construct. Components of the SOCON® Spinal System should NOT be used with components from any other system or manufacturer.

"Precaution: The implantation of the SOCON® Spinal System should be performed only by experienced spinal surgeons with specific training in the use of such spinal devices because the technique is a technically demanding procedure presenting a risk of serious injury to the patient."

Preamendments Device (legally marketed comparison device):

AESCULAP® Inc. believes that the SOCON® Spinal System is substantially equivalent to the SOCON® Spinal System described in Premarket Notification(s) K970285 and K993551. A basic feature comparison table for the SOCON® Spinal System is located at the end of this document.

Summary of Biomechanical Testing:
Fatigue testing of a "worst case" system configuration using 6.0mm screw constructs made of titanium was conducted. The testing demonstrates a significant improvement in performance for the modified SOCON® Spinal System screws as determined by the test model based on ASTM F-1717 - 96.

Summary Basis for Equivalence and Comparison Table:
Biomechanical studies conducted on the SOCON® Spinal System implant constructs demonstrate that the device system is safe, effective, and suitable for use as a spinal fixation device system. Based on the available information concerning the referenced comparison devices, these devices are similar in that:

- The devices have the same intended use and indications for use.
- The devices are made of the same implant alloy.
- The devices have similar form, function, components, instruments, dimensions, geometry and features.

The use of QSR based process controls, testing standards (ASTM F-1717 - 96 testing, materials standards (ASTM F-136, 92 and ISO 5832-3) and the similarities of the references comparison devices establish that the modified SOCON® Spinal System is substantially equivalent to the earlier SOCON® Spinal System.

Summary Comparison Table:

FEATURE	SOCON® Spinal System	SOCON® Spinal System	SE?
Indications for Use:	Indicated for the treatment of severe spondylolisthesis, (grades 3 & 4) of the L5-S-1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to Sacrum) with removal of the implants after the attainment of a solid fusion. Also: The devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).	SAME	YES
Components:	Pedicle screws, rod, nuts	SAME	YES
Sterility:	No. Steam sterilize on-site before use.	SAME	YES
Profile:	4.5mm lower	4.5mm higher	NO
Thread:	Tapered cancellous root diameter	Constant root diameter	NO
Spine Rods:	Hex drive end	No hex drive	NO
Materials:	Titanium alloy	SAME	YES
Attachment:	Posterior - Thoraco/lumbar spine	SAME	YES
Manufacturer:	Aesculap, AG & CO. KG	Aesculap, AG & CO. KG	YES
Surgical Approach:	Open	Open	YES
Product Code:	MNH, MNI	SAME	YES
K - Number:	Pending	K970285 - K993551	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2001

AESCULAPC, Inc.
Mr. David Schlerf
c/o Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K003463
SOCON Spinal System
Regulatory Class: II
Product Code: MNH, MNI
Dated: December 10, 2000
Received: March 12, 2001

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003463

Device Name(s): SOCON® Spinal System

Indications for Use:

When used as a posterior pedicle screw spinal system, the SOCON® Spinal System is indicated for patients requiring:

The treatment of severe spondylolisthesis, (grades 3 & 4) of the L5-S-1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to Sacrum) with removal of the implants after the attainment of a solid fusion.

Also:

The devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003463

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)